DEPARTMENT OF THE TREASURY



Procedure

# Voluntary Chemist Certification Program for the Analysis of Wine, Distilled Spirits, and Beer for Export

To: All Alcohol and Tobacco Tax and Trade Bureau (TTB) Regulated Alcohol Beverage Producers and Wholesalers, and Commercial Laboratories in the United States Who Analyze Alcohol Beverages for Export Purposes.

#### 1. What is the purpose of this Procedure?

The purpose of this Procedure is to provide information on the Alcohol and Tobacco Tax and Trade Bureau (TTB) Chemist Certification Program for the analysis of wine, distilled spirits, and beer for export.

#### 2. Does this Procedure supersede any previous guidance?

This Procedure supersedes TTB Procedure 2010–1.

#### 3. What is the TTB Chemist Certification Program and why is it useful?

The TTB Chemist Certification Program, established under the authority of section 105(e) of the Federal Alcohol Administration Act (FAA Act) (27 U.S.C. 205(e)), is a voluntary program that certifies private industry chemists to analyze alcohol beverages and report the results of specific chemical analyses on alcohol beverages to importing governments. As a condition of importation, some countries require that their own government laboratories (or laboratories certified by their government) perform these analyses, while other countries allow a person certified by the government of the exporting country to perform the analyses. TTB conducts the program as a service to the alcohol beverage industry to facilitate the export of domestic alcohol beverage products.

The Chemist Certification Program helps ensure that chemists, enologists, brewers, and technicians generate quality data and have the required proficiencies to conduct chemical analyses associated with exportation of alcohol beverages. A report of required analyses performed by the certified chemist accompanies the shipment of exported alcohol beverages.

#### 4. What changes have been made to Procedure 2010-1?

This procedure revises Procedure 2010-1 to incorporate certification guidelines and information for analyses of beer for export; to update eligibility guidelines for applicants; and to establish processes for audits of certified chemists and revocation of certification.

#### 5. How do I qualify to participate in the program?

- a. An applicant must be an employee or a laboratory proprietor, at a qualified laboratory, where the applicant will perform certification analysis in a capacity that satisfies the conditions found in this Procedure:
  - A qualified laboratory is a facility that is equipped with the proper tools and equipment to perform the required analyses (see question 11, below) for the certification of wine, distilled spirits, or beer. A qualified laboratory must also have quality control measures in place, and make available upon TTB's request, its written policies and procedures that ensure adequate quality of data produced by the laboratory for analyses (see questions 5.a.(2) and 5.a. (3), below) listed for certification.
  - (2) TTB reserves the right to verify (via on-site inspection, review of records, or otherwise) that the premises and equipment of a laboratory associated with the application for certification meet the qualifications set forth in question 5.a (1), above. This verification includes the availability and condition of equipment, equipment purchase and maintenance records, analyst training and competence records, laboratory quality system records, and sample analyses records pertaining to certified tests. These records must be available for 2 years after the period of the certification.
  - (3) Applicants who supervise personnel performing analyses for exportation purposes must meet the education requirements listed in 5.b., and satisfy requirements as described above, including making available to TTB, upon request, training records for personnel demonstrating their skills and knowledge for the task performed.

NOTE: Chemists who work in ISO 17025-accredited laboratories should refer to question 6, below, to learn how they can be certified under the program.

- b. First-time applicants to the program must submit a copy of their diploma and transcripts along with their application. Applicants must meet the minimum educational requirements detailed below:
  - (1) A Bachelor's degree in chemistry; OR
  - (2) An Associate's degree or Bachelor's degree in any physical, chemical, or biological science with at least 30 credits of chemistry; OR
  - (3) A Bachelor's degree in enology (for wine certification only); brewing (for beer certification only); or food sciences

- c. An applicant who obtains a degree from a foreign college or university must have the degree assessed by a U.S. organization (applicants may visit <u>https://www2.ed.gov/about/offices/list/ous/international/usnei/us/edlite-visitus-</u><u>forrecog.html</u> or <u>http://www.wes.org/jobseekers/</u> for guidance). The assessment should include:
  - (1) An evaluation of each diploma, indicating periods of education and U.S. equivalency for each document;
  - (2) A list of all subjects completed at the post-secondary level;
  - (3) A U.S. semester credit and grade equivalent for each course; and
  - (4) A U.S. grade point average (GPA) on a 4.0 scale.

## 6. What if the laboratory I work at is ISO 17025-accredited?

- a. ISO 17025 specifies the general requirements for the competence to carry out tests and calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods. Applicants who desire to be TTB-certified and are performing testing in a laboratory that is accredited under ISO 17025 may be eligible for certification without submitting a report of analysis of TTB-supplied test samples. Such applicants must:
  - (1) Meet the educational requirements set forth under question 5.b of this Procedure, and;
  - (2) Submit a copy of the accreditation certificate verifying the laboratory's current accreditation status, along with a list of methods under the scope of accreditation.
    - (a) If the laboratory is accredited to analyze wine, the scope of accreditation must cover the analyses listed in Table 11.1 for which the applicant wishes to be certified.
    - (b) If the laboratory is accredited to analyze distilled spirits, the scope of accreditation must cover the analyses listed in Table 11.2 for which the applicant wishes to be certified.
    - (c) If the laboratory is accredited to analyze beer, the scope of accreditation must cover the analyses listed in Table 11.3 for which the applicant wishes to be certified.

- b. Applicants who supervise personnel performing tests for export purposes must make available upon request to TTB training records for each employee, demonstrating skills and knowledge for the task performed.
- c. If a laboratory loses ISO 17025 accreditation during a certified chemist's 2-year approval period, or if any of the analyses listed in Tables 11.1, 11.2, or 11.3 that are listed on the laboratory's certificate are removed from the ISO 17025 accreditation scope, the TTB certification for the chemist will become void for those analyses. This will be effective from the date that a laboratory loses its ISO 17025 accreditation, or from the date that any analyses listed in Tables 11.1, 11.2, and 11.3 are removed. Should this occur, the laboratory manager (or delegate) must notify TTB immediately of any change to the accreditation status (see question 16 on how to reapply for certification).

## 7. How does the application process work?

TTB issues certificates twice each year (see question 8). TTB issues a call for applications via <u>TTB.gov</u>. The Bureau reviews all applicants for participation in the program. If an applicant meets the qualifications, TTB sends alcohol beverage samples for analysis. If the applicant does not meet the qualifications, TTB will contact the applicant in writing (by email) and provide the reason(s) the applicant did not qualify.

#### 8. When do I apply for the program?

The application cycles are in the fall and spring. TTB mails certificates to approved applicants in January and in July, respectively. Below is the timeline for each cycle.

	Fall Cycle Deadline	Spring Cycle Deadline
TTB posts a call for applications on TTB.gov	September 1	March 1
Applicants submit requests for participation to TTB on laboratory (or company) letterhead	October 1	April 1
TTB sends samples to qualified applicants	November 1	May 1
Applicants submit data packets to TTB	December 1	June 1
TTB notifies applicants of final decisions regarding certification	January 1	July 1

#### 9. How do I apply for the program?

- a. Applicants may send a letter via email (ChemistCertification@ttb.gov) on laboratory or company letterhead and addressed to Director, TTB, Scientific Services Division, to request to participate in the program.
  - (1) The request must include the following verification statements co-signed by the applicant and a laboratory manager who has authority to grant TTB access to inspect and audit the laboratory site(s) and documents.
    - (a) "(Name of qualified laboratory), under the direction of (insert name of manager in charge of laboratory seeking certification), authorizes TTB to verify by inspection or otherwise the laboratory's premises and equipment, documents related to training, analyses, and demonstration of competency of individual(s) performing testing associated with this application for certification."
    - (b) "(*Name of Applicant*) declares, under penalties of perjury, that the information provided to TTB in this application is true and correct."

NOTE: Failure to include the verification of information or perjury statement in an application will result in denial of certification.

- (2) In addition to the verification of information and perjury statement, the application letter must include the following:
  - (a) The commodity or commodities and the analyses for which the applicant is requesting certification. If no analyses are listed, TTB will assume the applicant is requesting certification for the entire list of analyses for the specified commodity or commodities, as set out in Tables 11.1, 11.2, and 11.3;
  - (b) The shipping address to which TTB will send test samples and the mailing address to which TTB will send the certificate;
  - (c) An email address for correspondence;
  - (d) Documentation that supports the educational qualifications of the applicant, including a copy of the applicant's diploma and transcripts, if TTB does not already have these on file (see question 5, above).
  - (e) The full name of the applicant (as it will appear on the certificate),
  - (f) The full name of the laboratory manager (as it will appear on the certificate), and

(g) The full name of the laboratory (as it will appear on the certificate).

NOTE: Applicants claiming ISO 17025 eligibility under question 6, above, must submit a copy of the laboratory's accreditation certificate verifying the current status along with a list of methods and tests under the scope of accreditation.

b. Applicants should send the above-listed items to:

ChemistCertification@ttb.gov.

- c. Applications must be received by the deadlines outlined in this Procedure (see question 8).
- d. For certification requests for analysis other than those listed in Tables 11.1 to 11.3, applicants must first be certified in at least one commodity (question 11). Refer to question 17 for further details on how to apply.

# 10. How do I know if I have been approved to participate in the certification process?

a. Applicants who meet the qualification requirements will receive a notice via email from TTB. The email notice will indicate that they have been approved to participate in the certification process and notify them of when to expect samples to arrive.

b. Applicants who do not meet the qualification requirements will receive a letter via email from TTB stating the reasons why the Bureau did not approve the application to participate.

# **11.** What do I do with the samples that I receive from TTB during the certification process?

#### a. Wine Program.

Applicants receive one 750 mL bottle for each type of wine (total 2 bottles) per testing cycle. Upon completion of the analyses, each participant submits his/her data via email using the wine reporting template provided for each wine analyzed. To ensure reliability of results, data should be obtained by a validated method (a method that has undergone a multi-laboratory performance study) or a method that is otherwise scientifically valid for the intended purpose. A scientifically valid method is among other things, accurate, precise, and specific for its intended purpose, and it has results that are consistently reliable and reproducible. The units of measurement required for reporting are in Table 11.1.

Analysis	Reported to the nearest:
Alcohol by Volume	0.1 percent by volume at 20°C
Total Extract	0.1 g/L
Total Acidity (Titratable) as Tartaric Acid	0.1 g/L
Volatile Acidity as Acetic Acid	0.1 g/L
Citric Acid	0.1 g/L
Total Sulfur Dioxide	1 mg/L
Residual Sugars (expressed as glucose + fructose)	0.1 g/L
Sorbic Acid	1 mg/L
Methanol	mg/L

Table	11.1
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#### b. Distilled Spirits Program.

Applicants receive one 750 mL bottle for each type of distilled spirit (total 2 bottles) per testing cycle. Upon completion of the analyses, each participant submits his/her data via email using the distilled spirits reporting template provided for each distilled spirits sample analyzed. To ensure reliability of results, data should be obtained by a validated method (a method that has undergone a multi-laboratory performance study) or a method that is otherwise scientifically valid for the intended purpose. A scientifically valid method is among other things, accurate, precise, and specific for its intended purpose, and it has results that are consistently reliable and reproducible. The units of measurement required for reporting are in Table 11.2.

<b>Table 11.2</b>
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Analysis	Reported to the nearest:	
Apparent Proof (determined without Obscuration)	0.1 degrees proof at 60°F	
True Proof (determined by Apparent		
Proof + Obscuration)	0.1 degrees proof at CO°E	
OR True Dreef (determined by	0.1 degrees proof at 60°F	
True Proof (determined by		
Distillation)	0.1 ~/1001	
Total Solids	0.1 g/100L	
Specific Gravity	0.00001 at 20°C	
Total Acidity as Acetic Acid	0.1 g/100L	
Methanol	0.01 percent by volume	
Ethyl Acetate	0.1 g/100L	
n-Propyl Alcohol	0.1 g/100L	
Isobutyl Alcohol	0.1 g/100L	
n-Butyl Alcohol	0.1 g/100L	
Amyl Alcohols (determined by iso-	0.1 g/100L	
Amyl Alcohol + active Amyl Alcohol)		
Furfural	0.1 g/100L	

#### c. <u>Beer Program.</u>

Applicants receive two types of beer in triplicate (total 6 bottles) per testing cycle. Upon completion of the analyses, the applicant submits his/her data via email using the beer reporting template provided for each beer analyzed. To ensure reliability of results, data should be obtained by a validated method (a method that has undergone a multi-laboratory performance study) or a method that is otherwise scientifically valid for the intended purpose. A scientifically valid method is among other things, accurate, precise, and specific for its intended purpose, and it has results that are consistently reliable and reproducible. The units of measurement required for reporting are in table 11.3.

Analysis	Reported to the nearest:
Alcohol by Weight	0.01 percent by weight
Real Extract	0.01 percent by weight
Specific Gravity	0.00001 at 20°C
pH	0.01
Bitterness Units	0.1 BU
Color	degree SRM

#### **Table 11.3**

#### **12.** Where do I submit my results after I complete the analysis?

Applicants must send completed analyses signed by the chemist performing the analysis and co-signed by a laboratory manager or supervisor. Send all results to:

#### ChemistCertification@ttb.gov

#### 13. What happens after I have submitted my results?

Once the applicant analyzes the samples and submits a data package to TTB, the Bureau then reviews the data and issues a final decision regarding the applicant's certification status.

#### 14. How do I know if I have been approved or denied certification?

#### a. Approval of Chemist Certification.

The successful applicant will receive an approval letter (via email) and signed certificate by mail. The letter and certificate will list the analyses the applicant is certified for and will identify the applicant, the laboratory manager, and the laboratory affiliated with the applicant.

#### b. Denial of Chemist Certification.

If an applicant's results do not fall within the established range determined for that cycle for a specific analysis, the applicant will receive a letter (via email) stating which analyses TTB did not approve for certification. The applicant's certificate will only list analyses the applicant is certified to perform. For applicants who fail all analyses, certification will be denied (see question 16 below) and the applicant will be notified via email. Acceptable ranges and study results will be made available to each participant.

#### 15. How long is my certification valid, and what do I do when it expires?

Chemist certification is valid for 2 years. Persons who wish to remain certified must reapply to the program before their current certification expires. For example, a person who applied and was certified on January 1, 2017, would need to apply for recertification in the fall cycle of 2018 in order to maintain certification. Persons who file an application for recertification on time may continue to operate under their existing certification pending final action on their application for recertification.

#### 16. What if I was denied certification for a particular analysis of interest?

Applicants who are denied certification for an analysis they requested are encouraged to reapply in the next cycle, which is when they may retest for failed analyses. However, applicants who reapply following denial of certification due to failure of results for two or more analyses must submit a root cause analysis with their new participation request. The root cause analysis should identify the cause of a failed result, document how it was remedied, and provide the corrective actions implemented to prevent future occurrence.

# 17. What if an importing country requires TTB-certified analytical data that is not listed in Tables 11.1, 11.2, or 11.3 in this procedure?

- a. If an importing country requires TTB-certified results of analyses other than those in tables 11.1, 11.2, and 11.3 of this Procedure, an individual who is already certified by TTB may apply to be certified in such an analysis as described below. The certified individual must notify the Director of the Scientific Services Division (SSD) by email (<u>ChemistCertification@ttb.gov</u>) with a request for additional certification. In these cases, there are additional qualifying requirements:
  - The notification must be a written request and must include the analyte(s) of interest <u>and</u> the analytical method(s) that will be used for testing;
  - (2) The notification must fall within one of the two certification periods, which begin January 1 and July 1 each year. Notifications must be received no later than:
    - (a) **October 1**, for TTB to process the application and certify the individual by **January 1**; or
    - (b) **April 1**, for TTB to process the application and certify the individual by **July 1**.
  - (3) The applicant must submit evidence that the analysis is required by the importing country. This can be verified by providing information on the importing country's website reflecting the requirement, or by submitting the exporter's request(s) stating that the analysis is required by a particular country.
  - (4) The applicant must submit a copy of the proposed method along with a current proficiency test demonstrating satisfactory results for the analyte(s) of interest as determined in the proficiency test report. Competency data (record showing that target level tested is achieved using the proposed method) for the applicant may be substituted for methods in which a commercial proficiency test is not available.

- (5) Applicants with ISO 17025 eligibility for Chemist Certification must submit a copy of the laboratory's accreditation certificate verifying current status along with the methods under the scope of accreditation. These applicants must also meet requirements defined above in question 6 when requesting certification for additional tests not listed in Tables 11.1-11.3 in this Procedure.
- (6) TTB will evaluate requests for certification of additional tests, and notify the applicant in writing (via email) regarding the certification status within 4-6 weeks of receiving notification.
- (7) Certified individuals must sign the report of analysis, if a signature is required by the country importing the product.

# 18. What do I do if I need a statement from the U.S. government on my laboratory report?

If a statement is required from a U.S. government official on the report of analysis prepared for a foreign country:

a. The certified individual may send the signed report of analysis to: Director, International Affairs Division (IAD), at

exportcertificates@ttb.gov or IAD@ttb.gov

b. The Director, IAD, or a designee, will attach the following statement to the report of analysis:

"The Alcohol and Tobacco Tax and Trade Bureau (TTB) of the U.S. Department of the Treasury confirms that the producer/exporter identified on this certificate holds a permit/registration/brewer's notice issued by TTB as identified by the permit/registry/brewer's notice number listed on this certificate and that the information about the exported product(s) is based on representations made by the producer/exporter."

c. TTB will retain one copy of the affirmed report of analysis, and will return the report to the certified chemist

# 19. What must I do to maintain my certification?

- a. To maintain certification during the 2 years in which the chemist is certified, the following conditions must be met:
  - (1) The chemist must perform and report tests for export analyses that appear on the TTB-issued certificate;

- (2) All records referenced under question 5, and all analytical results from analyses conducted under the authority of the TTB certificate during the effective time period (i.e., 2-year cycle) must be retained; *Provided*, that if the chemist has been certified for two or more consecutive periods, at least 2 years' worth of records and results must be retained, including any records and results from the previous certification period necessary to complete 2 years' worth of records; and
- (3) Upon TTB request, the certified chemist must agree to an on-site audit of laboratory premises, training documents, analytical data, and equipment relating to the testing of certification analytes.

NOTE: Failure to meet these requirements could result in revocation of certification (see question 22).

## 20. What if I no longer work at the laboratory where I obtained my certification?

- a. If, at any point during the 2 year certification period, a certified chemist is no longer employed by, or working on behalf of the qualified laboratory where the chemist obtained the TTB certification, the chemist must notify TTB immediately of the change in employment or working status.
- b. To maintain chemist certification after a change in employment, the following conditions must be met:
  - (1) A certified chemist may retain TTB Chemist Certification if that individual moves to another laboratory that already employs a TTB-certified chemist. Retention of certification status is contingent upon the subsequent laboratory's qualification as being equipped to perform analyses of the same type (i.e., wine, distilled spirits, or beer) for which the individual is certified.
  - (2) The certified chemist must notify the Director, SSD, of the change in employment status or working conditions on the subsequent laboratory's (or company's) letterhead.
  - (3) The applicant and the appropriate laboratory official must submit a signed copy of the verification of information statements listed in question 9 of this procedure.
- c. TTB will evaluate the applicant's claims and issue an updated certificate that identifies the certified individual and the new qualified laboratory.
- d. If the certified individual wishes to remain certified beyond 2 years, that person must reapply for certification before their original 2-year certification period expires.

e. A certified chemist who moves to a laboratory that is not under the Chemist Certification Program will need to reapply for certification.

## 21. What reasons could result in denial of my certification?

- a. Reasons for denial of a certificate include, but are not limited, to the following:
  - (1) Your application is incomplete (see question 9).
  - (2) You do not meet education eligibility requirements (see question 5).
  - (3) Your performance test results were out of the established tolerance range (see questions 14 and 16).
  - (4) You, or the laboratory where you work, do not agree to an audit pertaining to analysis under certification (see question 19).
  - (5) During the application or reapplication process, you, or a certified chemist in the laboratory where you work, are under consideration for certificate revocation, or there are unresolved issues resulting from a finding at the laboratory where you work (see questions 16 and 22).

## 22. What reasons could result in revocation of my certification?

- a. Reasons for revocation of a certificate include, but are not limited, to the following.
  - (1) You provide false, erroneous, fictitious, fraudulent, or otherwise deceptive analytical data or information (this includes reporting data from another laboratory or chemist as your own) to TTB or as part of an analysis conducted under the Chemist Certification Program.
  - (2) You make false, erroneous, fictitious, fraudulent, or otherwise deceptive statements on your application.
  - (3) You make false, erroneous, fictitious, fraudulent, or otherwise deceptive statements regarding your certification status (this includes misrepresentations, explicit or implied, regarding the scope of your certification).
  - (4) You fail to meet the requirements in question 19 of this procedure.
  - (5) You, or the laboratory where you work, do not agree to an audit pertaining to an analysis under certification.

- (6) The following type of findings occur during an audit, for example:
  - (a) Those under your supervision are not properly trained to run analyses under the Chemist Certification Program; or
  - (b) Your laboratory's policies and procedures for testing do not ensure that quality requirements are met (see question 5 above).

#### 23. What are the procedures for revoking certification?

- a. TTB will send a notice of proposed revocation (by registered or certified mail) to the contact person provided in the chemist's application. The notice will set forth the reason(s) for which TTB is considering revocation of the chemist's certification.
- b. A chemist whose certification is under consideration for revocation may send a written response on laboratory or company letterhead challenging a notice of proposed revocation. The response must:
  - (1) Be sent within 30 days of receipt of the notice of proposed revocation;
  - (2) Be sent to the TTB address indicated in the notice of proposed revocation;
  - (3) Set forth any and all arguments, explanations, or reasons for which the chemist believes that his or her certification should not be revoked; and
  - (4) Be co-signed by a laboratory manager who has authority to grant TTB access to inspect and audit the laboratory site(s) and documents.
- c. Within 30 days of receipt of a response to a notice of proposed revocation, TTB will make a decision and notify the chemist in writing (by registered or certified mail).
- d. TTB will update its website list of certified chemists and qualified laboratories to reflect changes, as they occur.
- e. The duration of the revocation penalty will depend upon relevant mitigating and aggravating factors, but, at a minimum, will consist of certificate revocation for one cycle during the year. For example, the submission of material false or fraudulent information may result in termination of participation in the Chemist Certification program.

#### 24. How do I reapply for certification after my certificate is revoked?

a. Depending on the reason the certification was revoked, TTB may request an onsite audit before an applicant may recertify for the program.

b. The laboratory will need to provide documentation to verify that the problem has been resolved.

# 25. Where can I find a list of TTB-certified chemists?

The current list of certified individuals and qualified laboratories is available at:

https://www.ttb.gov/ssd/chemist\_certification.shtml

The list is updated regularly, so please check frequently.

# 26. Who do I contact if I have questions?

If you have any questions regarding this Procedure, please contact TTB by email at:

ChemistCertification@ttb.gov

John J. Manfreda Administrator Alcohol and Tobacco Tax and Trade Bureau